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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,408	12/12/2003	Richard Storer	06171.105064 IDX 1024	2099
20786	7590	12/22/2006		
KING & SPALDING LLP 1180 PEACHTREE STREET ATLANTA, GA 30309-3521			EXAMINER KRISHNAN, GANAPATHY	

ART UNIT	PAPER NUMBER
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/22/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

DETAILED ACTION

Applicant's election without traverse of Group II, claims 20-28, 31-44, 50, 64-68 and 89-90 in the reply filed on 9/21/2006 is acknowledged. Claims 1-19, 29-30, 45-49, 51-63 and 69-88 have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of ribofuranose from D-fructose, does not reasonably provide enablement for the preparation of a ribofuranose from any cyclic ether. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

- (A) The breadth of the claims
- (B) The state of the prior art
- (C) The level of one of ordinary skill
- (D) The level of predictability in the art
- (E) The amount of direction provided by the inventor
- (F) The existence of working examples
- (G) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

Claim 20 (a) recites reaction of a cyclic ether containing a hydroxyl and a CH₂OH on the carbon adjacent to the ring oxygen, with CaO to form a furanyl lactone, which is further converted to a furanose product. The cyclic ether as recited above is also seen to include an ether containing a hydroxyl and a CH₂OH only on the carbon adjacent to the ring oxygen but not on the other ring carbons and the term cyclic ether is also seen to include rings other than 6-membered rings.

The state of the prior art

The examiner notes that BeMiller et al (Methods in Carbohydrate Chemistry, 1963, 2, 484-485) teaches the conversion of a six membered cyclic ether (open chain form shown in the reference) to a furanose. The prior art is silent regarding the same transformation using a cyclic ether other than a six membered ether.

The level of predictability in the art

The examiner acknowledges the probability that the instantly claimed process may have a reasonable expectation of success. There is not seen sufficient data to substantiate that such a transformation would be successful using any cyclic ether.

The amount of direction provided by the inventor

The instant specification is not seen to provide enough guidance that would allow a skilled artisan to extrapolate from the disclosure and the examples provided to enable the formation of a furanose product from any cyclic ether.

The existence of working examples

The working examples set forth in the instant specification are drawn to the formation a methyl substituted ribofuranose from fructose, which is a six membered cyclic ether (cyclic form of fructose). There are no other examples of preparing a furanose starting with a cyclic ether other than fructose. One of ordinary skill in the art would not extrapolate the preparation of a furanose from fructose to all other cyclic ethers as starting material for the said preparation.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable the preparation of a ribofuranose from any cyclic ether other than fructose. One of ordinary skill in the art would have to carry out the process in order to determine which cyclic ether, if any, other than fructose will yield the desired furanose product.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 (a) recites reaction of a cyclic ether containing a hydroxyl and a CH_2OH on the carbon adjacent to the ring oxygen, with CaO to form a furanyl lactone, which is further converted to a furanose product. A furanose is a five membered cyclic sugar, having hydroxyls attached to the other ring carbons in addition to the carbon adjacent to the ring oxygen. The

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cyclic ether as recited above is also seen to include an ether containing a hydroxyl and a CH₂OH only on the carbon adjacent to the ring oxygen but not on the other ring carbons. Such an ether will not lead to a furanose product as instantly claimed. It is not clear what applicants intend.

Claims that depend from a rejected base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-28, 36, 50 and 64-67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 10/882,893 ('893 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

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Instant claims 20-25, 27-28, 36, 50 and 64-67 are drawn to a process wherein one of the steps involved is the reduction of a lactone carbonyl group to the corresponding alcohol using a reducing agent, one of which is lithium tri(t-butoxy)aluminum hydride. Claim 1 of the copending application is drawn to the same process step wherein a ribonolactone is reduced with RED-Al (sodium bis(2-methoxyethoxy)aluminum hydride to the corresponding alcohol.

Instant claim 26 recites toluoyl as one of the protecting groups. The same recitation is also seen in claim 2 of the copending '893 application.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that instant claims 20-25, 27-28, 36, 50 and 64-67 are overlapping with claims 1-2 of the copending '893 application.

One of ordinary skill in the art knows that both the reducing agents achieve the same reduction via a hydride and would work with a reasonable expectation of success on both ribonolactones since they are structurally very close and the said reduction takes place only at the carbonyl group.

Instant claims 20-25, 27-28, 36, 50 and 64-67 should recite limitations that are patentably distinct from those of claims 1-2 of the copending '893 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-28, 31-44, 50, 64-68 and 89-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over BeMiller et al (Methods in Carbohydrate Chemistry, 1963, 2, 484-485, IDS document # HK) in combination with The Merck Index (12th edition, 1996, page 275), Sundberg et al (Advanced Organic Chemistry, Part B, 1990, pages 232 and 236), McFarlin (J. Am. Chem. Soc. 1958, 80, 5372—76) and Piccirilli et al (J. Org. Chem. 1999, 64, 747-54; IDS document # HH).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

BeMiller et al teach the conversion of D-fructose (I) to 2-C-methyl-D-ribonolactone (II). The transformation is effected at room temperature using calcium hydroxide (aqueous), carbon dioxide and oxalic acid (pages 284-285, Procedure). However, BeMiller et al do not teach specifically the use of aqueous CaO, the reduction of the carbonyl group of the ribonolactone or the formation of the benzoyl derivative of the furanose.

The Merck Index teaches that calcium oxide is soluble in water forming calcium hydroxide (page 275, entry # 1733). Hence, reacting aqueous CaO with the cyclic ether or fructose as instantly claimed is same as the reaction taught by BeMiller et al.

Sundberg et al teach the reduction of a lactone carbonyl to the corresponding alcohol using alkoxyaluminumhydride reagent (page 236). Even though the reducing agent is not lithiumtri(t-butoxy)aluminum hydride as instantly claimed, one of ordinary skill in the art will recognize that it is very similar. Sundberg et al also teach (page 232, Table 5.2) that lithiumtri(t-butoxy)aluminum hydride also reduces a carbonyl group to an alcohol.

According to McFarlin et al teach that lithiumtri(t-butoxy)aluminum hydride is very stable and a mild reducing agent and is soluble in several solvents (page 5372 abstract; page 5373, Table I).

Piccirilli et al teach benzoyl derivative of ribofuranose (page 748, structure 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the prior art and use it in the processes as instantly claimed since the steps and reagents for the same is seen to be taught in the prior art.

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One of ordinary skill in the art would be motivated to use the process of the prior art since the process for the preparation of the lactone and the corresponding alcohol as taught by the prior art involve simple manipulations and the use of mild reagents as taught by McFarlane. It is well within the purview of one of ordinary skill in the art to extend the scope of the process to other solvents and reagents (reducing agents and protecting groups) for the purpose of optimizing the yield of the desired product and the process steps. It is also well known in the art to speed up reactions by using higher temperatures.

Conclusion

Claims 20-28, 31-44, 50, 64-68 and 89-90 are rejected

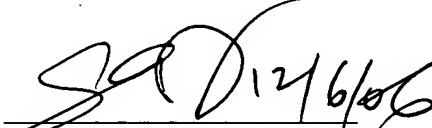
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK


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Supervisory Patent Examiner
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